Translation

PATENT COOPERATION TREATY

PCT/JP2003/000328

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

16 JUL 2004

Applicant's or agent's file reference 03-004-PCT	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/JP03/00328	International filing date (*day/month/year*) 17 January 2003 (17.01.03)	Priority date (*day/month/year*) 17 January 2002 (17.01.02)
International Patent Classification (IPC) or national classification and IPC C12N 15/55, 9/12, C12Q 1/68, 1/34		
Applicant TANABE SEIYAKU CO., LTD.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
17 January 2003 (17.01.03)	02 June 2003 (02.06.2003)
Name and mailing address of the IPEA/JP Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/JP03/00328

I. Basis of the report

1. With regard to the elements of the international application:*

☒ the international application as originally filed

☐ the description:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the claims:

pages _____, as originally filed
pages _____, as amended (together with any statement under Article 19
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the drawings:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the sequence listing part of the description:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☒ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☒ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____
☐ the claims, Nos. _____
☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/JP03/00328

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 18-20, 22-30

because:

☒ the said international application, or the said claims Nos. 18, 19, 22-24, 26-30 relate to the following subject matter which does not require an international preliminary examination *(specify)*:

The inventions of claims 18, 22-24, and 26-30 concern a method for diagnosis and treatment of the human body by therapy.

The method for selling described in the invention of claim 19 concerns a scheme, rule, method of doing business, or performing a purely mental act.

☒ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. 18-20, 22-26 are so unclear that no meaningful opinion could be formed *(specify)*:

Although the Specification states that the "inventive substance that inhibits phospholipase A_2" in the claims corresponds to the inhibitor of methyl arachidonyl fluorophosphonate in the Examples, it does not restrict this description to specific chemicals (or group thereof). This being the case, it is entirely unclear which specific compounds are included and which are excluded from the scope of the "inventive substance that inhibits phospholipase A_2" of claim 8, and the description of this claim is exceedingly vague.

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 18-20, 22-30.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/JP03/00328

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	6-17	YES
	Claims	1-5, 21	NO
Inventive step (IS)	Claims		YES
	Claims	1-17, 21	NO
Industrial applicability (IA)	Claims	1-17-21	YES
	Claims		NO

2. Citations and explanations

Document 1: US 6287838 B (GENTIS INSTITUTE, INC) September 11, 2001
Document 2: US 6025178 A (ELI LILLY AND COMPANY) February 15, 2000
Document 3: Song C, et al., Molecular characterization of cytosolic phospholipase A2-beta, J Biol Chem. (1999), Vol. 274, No. 24, p. 17063-17067
Document 4: Pickard RT, et al., Molecular cloning of two new human paralogs of 85-kDa cytosolic phospholipase A2, J Biol Chem. (1999), Vol. 274, No. 13, p. 8823-8831

Claims 1-5 and 21

Document 1 describes the inventions of claims 1-5 and 21, and therefore these inventions lack novelty.

Document 1 describes a cellular phospholipase A_2 having 50% homology with the amino acid sequence identified as SEQ ID NO: 9 in this application and 63% homology with the base sequence identified as SEQ ID NO: 8 in this application. Document 1 also states that phospholipase A_2 inhibitors are used in the treatment of inflammatory diseases such as psoriasis and rheumatoid arthritis.

Claims 14-17

Based on the description in document 1, the inventions of claims 14-17 lack an inventive step.

This examination finds that preparing an antibody to a peptide with a publicly known amino acid sequence presents no technical difficulty to persons skilled in the art, and because document 1 states that phospholipase A_2 inhibitors are used in the treatment of inflammatory diseases such as psoriasis and rheumatoid arthritis, persons skilled in the art can easily conceive of screening to obtain compounds that inhibit the phospholipase A_2 described in document 1 as medicines to treat inflammatory diseases such as psoriasis and the like.

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of Box V:

Claims 1-5 and 21

Document 2 describes the inventions of claims 1-5 and 21, and therefore these inventions lack novelty.

Document 2 describes a cellular phospholipase A_2 having 49% homology with the amino acid sequence identified as SEQ ID NO: 2 in this application, and it describes the use of phospholipase A_2 in the development of medicines to treat inflammatory diseases.

Claims 14-17

Based on the description in document 2, the inventions of claims 14-17 lack an inventive step.

This examination finds that preparing an antibody to a peptide with a publicly known amino acid sequence presents no technical difficulty to persons skilled in the art, and that persons skilled in the art can easily conceive of screening to obtain compounds that inhibit the phospholipase A_2 described in document 2 as medicines to treat inflammatory diseases.

Claims 1-17 and 21

Based on the descriptions in documents 1-4, the inventions of claims 1-17 and 21 lack an inventive step.

Documents 3 and 4 describe a cellular phospholipase A_2 having 63% homology with the base sequence identified as SEQ ID NO: 8 in this application.

This examination finds that persons skilled in the art can easily conceive of obtaining a novel phospholipase A_2 from the base sequences and amino acid sequences of the phospholipase A_2 isozymes described in documents 1-4 and phospholipase A_2 isozymes that were publicly known prior to the filing date of this application, determining the base sequence and amino acid sequence of that enzyme, preparing a vector containing that base sequence and transfecting cells with that vector to produce a recombinant polypeptide, preparing antibodies to that polypeptide, and screening to obtain compounds that inhibit phospholipase A_2 to obtain medicines to treat inflammatory diseases.